AO 120 (Rev. 3/04)

SOLICITOR

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AUG 10 2007
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In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Central District on the following [X] Patents or [ ] Trademarks:

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FILED

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
2895 SJO	May 12, 2006	Central District of California

PLAINTIFF	DEFENDANT
SICOR PHARMACEUTICALS, INC., a Delaware corporation	ELI LILLY & Co., an Indiana corporation

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	4,808,614	2/28/1989	Eli Lilly & Co.
2	5,464,826	11/7/1995	Eli Lilly & Co.
3			
4			
5			

In the above-entitled case, the following patent(s)/trademark(s) have been included:

DATE INCLUDED

INCLUDED BY [ ] Amendment [ ] Answer [ ] Cross Bill [ ] Other Pleading

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1			
2			
3			
4			
5			

DOCKETED ON CM
AUG 8 2007
BY 021

DOCKETED ON CM
MAY 17 2006
BY 019

In the above-entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

Order Granting Defendant's Motion To Dismiss Plaintiff's Complaint & Denying Plaintiff's Cross-Motion For A Stay

CLERK	(BY) DEPUTY CLERK	DATE
SHERRI R. CARTER		AUG - 8 2007

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**

AO-120

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SICOR PHARMACEUTICALS, INC., Plaintiff, v. ELI LILLY AND COMPANY, Defendant.	NO. CV 06-2898 SJO (VBKx) **ORDER GRANTING DEFENDANT'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT AND DENYING PLAINTIFF'S CROSS-MOTION FOR A STAY**

On June 30, 2006, Defendant Eli Lilly and Company ("Eli Lilly") filed a Motion to Dismiss Plaintiff's Complaint pursuant to Federal Rule of Civil Procedure 12(b)(1) ("Rule 12(b)(1)"). Plaintiff Sicor Pharmaceuticals, Inc. ("Sicor") has filed an Opposition to Defendant's Motion and, in the alternative, a Cross-Motion for a Stay. Defendant Eli Lilly has filed a Reply to Plaintiff's Opposition and an Opposition to Plaintiff's Cross-Motion for a Stay. Having carefully and thoroughly considered the arguments raised in support of and in opposition to the instant Motion and Cross-Motion, the Court deemed these matters appropriate for decision without oral argument. *See* Fed. R. Civ. P. 78; Local Rule 7-15. For the following reasons, the Court GRANTS Defendant's Motion and DENIES Plaintiff's Cross-Motion.

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I. FACTUAL BACKGROUND

Plaintiff Sicor is in the business of developing, manufacturing and marketing injectable pharmaceutical products. (Rosenberg Decl. ¶ 4.) Sicor filed Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration ("FDA") seeking approval to market injectable gemcitabine products generic to Lilly's Gemzar anti-cancer drug. Sicor alleges that its principal place of business is in Irvine, California. (Mortazavi Decl. Ex. A.) It claims it does not have a regular and established place of business in the Southern District of Indiana or elsewhere in Indiana. (Rosenberg Decl. ¶ 5.)

On February 15, 2006, Eli Lilly brought an action for patent infringement against Sicor in the United States District Court for the Southern District of Indiana, in which Eli Lilly alleged that Sicor's proposed manufacture and sale of injectable gemcitabine products would infringe two of Eli Lilly patents. (Bishop Decl. Ex. A.) Sicor has moved to dismiss the action in the Indiana district court for lack of personal jurisdiction, or, in the alternative, to transfer the case to this Court. The Indiana district court has not yet ruled on Sicor's motion.

On May 12, 2006, Sicor filed this action against Eli Lilly for declaratory judgment of non-infringement and declaratory judgment of invalidity. On June 30, 2006, Eli Lilly filed the instant Motion to Dismiss pursuant to Rule 12(b)(1) alleging that, under § 355(j)(5)(C)(i)(II) of the Hatch-Waxman Act, Sicor is barred from filing a declaratory judgment action since Eli Lilly has already filed an action for patent infringement, which is now pending in the Southern District of Indiana.

II. REGULATORY BACKGROUND

This case involves the statutory framework governing new and generic drug approvals and its mechanisms for patent enforcement, which the Federal Circuit described at length in *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (2002). For the purposes of this Motion, it is appropriate to explain the regulatory framework in detail here.

Under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), a pharmaceutical company seeking to manufacture a new drug is required to file a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355(a) (1994). The NDA must contain detailed

clinical studies of the drug's safety and efficacy and a list of patents which claim the drug. *See id.* § 355(b)(1) (Supp. V 1999).

If the FDA approves the NDA, it publishes a listing of the drug and patent on the drug's approved aspects in *Approved Drug Products with Therapeutic Equivalence Evaluations*--what is commonly referred to as the "Orange Book." *Id.* § 355(j)(7)(A)(iii) (1994); *id.* § 355(b)(1); *see also* 21 C.F.R. § 314.53(c)(2)(ii) (2001).

Pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), *codified at* 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282 (the "Hatch-Waxman Amendments" to the FFDCA and to Title 35 of the United States Code relating to patents), a pharmaceutical manufacturer seeking approval to market a generic version of a previously approved drug may submit an ANDA to the FDA. 21 U.S.C. § 355(j) (1994). An ANDA offers an expedited approval process for generic drug manufacturers. Rather than filing a full NDA with new safety and efficacy studies, in an ANDA a generic manufacturer may rely in part on the pioneer manufacturer's work by submitting data demonstrating the generic product's bioequivalence with the previously approved drug. *See id.* § 355(j)(2)(A) (Supp. V 1999).

These provisions from the Hatch-Waxman Amendments "emerged from Congress' efforts to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to the market." *Abbott Labs v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting on other grounds). As the Federal Circuit recognized, the Hatch-Waxman provisions concerning patent infringement are part of this balance, for it is not infringement to conduct otherwise infringing acts necessary to prepare an ANDA. *Mylan Pharmaceuticals, Inc.*, 268 F. 3d at 1326; *see also* 35 U.S.C. § 271(e)(1) (Supp. V 1999) ("It shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.").

Under § 271(e)(2), however, a generic drug manufacturer infringes by filing an ANDA to obtain FDA approval for the purpose of marketing a generic drug product claimed in a patent before the patent expires. 35 U.S.C. § 271(e)(2) (1994) ("It shall be an act of infringement to submit . . . [an ANDA] . . . if the purpose of such submission is to obtain [FDA] approval . . . to engage in the *commercial* manufacture, use, or sale of a drug . . . claimed in a patent before the expiration of such patent.") (emphasis added).

As part of the ANDA process, an applicant seeking to market a generic version of a listed drug must make a certification as to each patent listed in the Orange Book which "claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(vii) (1994). Further, according to regulations enacted by the FDA, an applicant whose ANDA is pending when a pioneer drug manufacturer lists additional patents in the Orange Book must make certifications as to the new patents, unless the additional patents are submitted more than thirty (30) days after they were issued. 21 C.F.R. § 314.94(a)(12)(vi) (2001).

The applicant must then certify either that: (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) such patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV) (1994). These are commonly referred to as Paragraph I, II, III, IV certifications. Further, if one of the listed patents is a method-of-use patent which does not claim a use for which the applicant is seeking approval, the applicant must make a statement to that effect (a "Section viii Statement"). *Id.* § 355(j)(2)(A)(viii).

An ANDA containing a Paragraph I or II certification may be approved without additional delay. *See* 21 U.S.C. § 355(j)(5)(B)(i) (Supp. V 1999). An ANDA containing a Paragraph III certification indicates that the applicant does not intend to market the drug until after the expiration of the patent, and the approval of the ANDA cannot be made final until the patent expires. *Id.* § 355(j)(5)(B)(ii).

When an ANDA contains a Paragraph IV certification, the ANDA applicant must give notice to the patentee and must provide detailed bases for its belief that the patent is invalid, unenforceable, or not infringed. *Id.* § 355(j)(2)(B)(i); 21 C.F.R. § 314.95(c)(6) (2001). The patentee is then given forty-five (45) days to sue the ANDA applicant for infringement. 21 U.S.C. § 355(j)(5)(B)(iii) (Supp. V 1999). If the patentee does not file suit, the application may be approved. If the patentee files suit within that period, the FDA may not approve the ANDA until the expiration of the patent, judicial resolution of the infringement suit, a judicial determination that the patent is invalid or unenforceable, or thirty (30) months from the patentee's receipt of notice, which comes first. *Id.*; 21 C.F.R. § 314.107(b)(1)(iv) (2001). Moreover, the availability of declaratory judgment actions is limited: "Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of Title 28, for a declaratory judgment with respect to the patent." *Id.* These provisions give the pioneer manufacturer the first opportunity to file suit against the ANDA applicant for infringement, and may substantially delay the ANDA approval during the pendency of the litigation.

III. DISCUSSION

A. Section 355(j)(5)(C)(i)(I) of Title 21 of the United States Code Bars Plaintiff Sicor's Action for Declaratory Relief.

Defendant Eli Lilly argues that this Court lacks subject matter jurisdiction because, under § 355(j)(5)(C)(i)(I), Plaintiff Sicor cannot bring a declaratory judgment action unless Eli Lilly's action for patent infringement in the Souther District of Indiana is dismissed without prejudice. For the following reasons, the Court finds this argument persuasive.

The Hatch-Waxman Act, as amended, prohibits the filing of a declaratory judgment action where, as here, the NDA holder files a patent infringement action within the specified forty-five (45) day period. Section 355(j)(5)(C)(i)(I) provides in relevant part:

> No action may be brought under section 2201 of Title 28 [the Declaratory Judgment Act] by an applicant [filing an ANDA] for a declaratory judgment with respect to a patent which is the subject of [a Paragraph IV certification] . . . unless neither the owner of such patent nor the holder of the approved [NDA] brought a civil action against the applicant for infringement of the patent before the expiration of [45 days from receipt of notice].

In the instant case, Plaintiff Sicor does not dispute that Defendant Eli Lilly filed an action for patent infringement within forty-five (45) days of receiving notice of Sicor's Paragraph IV certifications. Because Eli Lilly brought a patent infringement action against Sicor in the Southern District of Indiana forty-two (42) days after receiving notice of Sicor's first Paragraph IV certification (Bishop Decl. Ex. A, Civil Action No. 06-CV-0238-B/S), § 355(j)(5)(C)(i)(II) bars Sicor from bringing an action for declaratory judgment.

Sicor argues that, "under 21 U.S.C. § 355(j)(5)(C)(i)(II), an ANDA applicant is not barred from bringing a declaratory judgment action prior to dismissal of a 'civil action' brought by a patent owner or NDA holder *unless* such 'civil action' was brought in a judicial district in which the ANDA applicant has its principal place of business or regular and established place of business." (Pl.'s Opp'n 7.) In support of this argument, Sicor references the venue provision for declaratory judgment actions authorized in § 355(j)(5)(C)(i)(II), which provides that "a civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business."

The Court does not find Sicor's argument persuasive. Sicor's reading of § 355 contradicts the plain language of the statute. Section 355(j)(5)(C)(i)(I) states on its face that an ANDA applicant cannot bring a declaratory judgment action if, during the forty-five (45) day period the patentee or NDA holder brings an action for patent infringement against the ANDA. In view of the statute's plain language, it is likely Congress simply intended for the venue provision to apply to ANDA actions for declaratory judgment against patentees or NDA holders. Moreover, as Defendant suggests, Sicor's interpretation would allow for two lawsuits pertaining to the same dispute to take place in separate courts. (Def.'s Reply 5.) This would significantly undermine Congress's attempt at providing the pioneer manufacturer with the first opportunity to file suit and control of the litigation. *See Mylan Pharm., Inc.*, 268 F.3d at 1327. For these reasons, the Court GRANTS Defendant's Motion without prejudice.

B. A Stay Is Not Warranted Under the Circumstances.

In the alternative, Plaintiff Sicor requests this Court to grant "a stay of this action until the Indiana court decides Sicor Pharma's motion to dismiss." (Pl.'s Opp'n 9.) As Plaintiff points out,

the power to stay proceedings is normally an incidental power inherent in every court to control the disposition of the cases on its docket. *Id.* However, where, as here, the Court lacks subject matter jurisdiction at the outset of the litigation, the Court can do nothing except dismiss the present action. *See Morongo Band of Mission Indians v. Cal. State Bd. of Equalization*, 858 F.2d 1376, 1380 (9th Cir. 1988) ("If jurisdiction is lacking at the outset, the district court has 'no power to do anything with the case except dismiss.'"). Accordingly, the Court DENIES Plaintiff's Cross-Motion for a Stay.

IV. CONCLUSION

For the foregoing reasons, the Court GRANTS Defendant Eli Lilly's Motion to Dismiss Plaintiff's Complaint without prejudice. The Court also DENIES Plaintiff Sicor's Cross-Motion for a Stay. The clerk shall close the file.

IT IS SO ORDERED.

Dated this 22 day of August, 2006.

S. JAMES OTERO
UNITED STATES DISTRICT JUDGE